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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,858	08/25/2000	Michael Dittgen	388A	5905

7590 05/20/2003

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HUNTINGTON, NY 11743

EXAMINER

BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/20/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/648,858

Applicant(s)

DITTGEN ET AL.

Examiner

Mojdeh Bahar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 7, 2003 has been entered.

Applicant's terminal disclaimer has overcome the obviousness double patenting rejection in the previous office action.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Embase Abstract -272 in view of WPIDS abstracts -924 and -225, all references of record in parent application 08/738314, now USPN 6,133,251.

The Embase Abstract -272 teaches that triphasic estrogen/gestagen contraceptives are known in the art, see abstract. The claims differ primarily in that they are drawn to compositions and methods employing an estrogen, an estrogen in combination with a gestagen, an estrogen, and a placebo sequentially for specified periods of time. The WPIDS abstracts -924 teaches that

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the employment of estrogens (which may be natural) sequentially with an estrogen/gestagen combination in contraceptives is known.

One of ordinary skill in the art would have been motivated to employ the estrogen and estrogen/gestagen combination preparations of the WPIDS abstracts -924 in a triphasic method and/or preparation varying the dose of estrogen administered at different times in the cycle, since the benefits of varying estrogen doses in this way were known in the art. Triphasic estrogen/gestagen preparations were known broadly in the art to be useful means of contraception, see WPIDS abstract -225. Note also that the employment of medroxyprogesterone as the gestagen component of a contraceptive regimen is well known, see WPIDS abstract -225. Variations or optimizations of the dosage regimen of compounds well known to be administered together sequentially and in combination, are considered within the skill of the artisan.

### ***Response to Arguments***

Applicant's arguments filed March 7, 2003 have been fully considered but they are not persuasive. Applicant states that an IDS form has been filed with the response of 03/07/03. Note that no IDS has been filed. Applicant refers to the declaration submitted under 37 CFR 1.132, in the parent application and resubmitted in the present application on 03/12/02 and applicant's arguments based thereon have been considered, but are not found persuasive to overcome the obviousness rejection. Note that as stated in the previous action, the comparative data provided in the instant declaration compares *one specific regimen, one specific estrogen and one specific progestin* claimed herein. i.e., 3 days of 3 mg of estradiol valerate alone, 4 days of a combination of 2 mg of estradiol valerate and 1 mg of dienogest, 16 days of a combination of 2 mg of

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estradiol valerate and 2 mg of dienogest, 2 days of 1 mg of estradiol valerate and three days of placebo. This showing is not commensurate in scope with the claims of the instant application, thus the declaration is not persuasive to remove the obviousness rejection. Note that the instant claims are BROADER than those of the parent case.


In his response, applicant argues that the administration of one estrogen leads to amounts of the other estrogens being produced. Applicant relies on an information disclosure statement and its references to support this proposition. Note that Ids has been filed and thus the teachings of the documents therein cannot be reviewed. Applicant has submitted a one page schematic representation attached to the response. Note that this page is illegible. Examiner has tried her best to decipher this representation, but cannot reach a conclusion since the arrows showing interconversion are not clearly depicted in the sheme.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar  
Patent Examiner  
May 6, 2003

  
SREENI PADMANABHAN  
PATENT EXAMINER

5/18/03